

**REMARKS**

The pending Office Action addresses claims 1, 2, 7-10, 13-20, 42, 43, and 46-50. Claims 1, 2, 7-10, 13-20, 42, 43, and 46-50 stand rejected.

***Claim Amendments***

Claims 1, 42, and 43 are amended to include some of the limitations of claim 14, and in particular to recite a mating element adapted to extend through the male and female connectors. Claims 1, 42, and 43 are also amended to replace the term "locking mechanism" with "fastening element" and to clarify that the fastening element mates to at least one of the male and female connectors. Claim 46 is also amended to replace the term "locking mechanism" with "fastening element." No new matter is added. Claims 7 is amended to remove the changes made in the previous response, and claim 8 is amended to recite that the first elongate member is a spinal fixation plate and the second elongate member is a spinal fixation rod. Claims 14, 15, 17, and 18 are amended to correspond to amended claim 1.

***Rejections Pursuant to 35 U.S.C. §112***

Claims 7 and 8 are rejected pursuant to 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. As indicated above, claims 7 and 8 are amended to correct the error pointed out by the Examiner, thereby obviating the basis for this rejection.

***Rejections Pursuant to 35 U.S.C. §102***

*(1) U.S. Patent No. 5,509,328 of Lai*

Claims 1, 2, 13-20, 42, 43, 46, 48, and 49 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,509,328 of Lai.

Independent claim 1 is directed to a spinal fixation device including a first elongate member having a female connector with opposed arms and a second elongate member having a male connector adapted to mate to the female connector. The first and second elongate members couple to one another such that the first and second elongate members are angularly adjustable relative to one another. The device also includes a mating element adapted to extend through the male and female connectors, and a fastening element adapted to mate to at least one of the male and female connectors to lock the elongate members in a fixed position relative to one another. At least one of the first and second elongate members is a spinal fixation rod. Similar to claim 1, claims 42, 43, and 46 also recite that at least one of the first and second elongate members is a spinal fixation rod.

Lai does not teach a spinal fixation device, much less a device having a spinal fixation rod. Lai discloses an adjustable bicycle handlebar tube having a head tube (10) with two circular lugs (13) formed on one end, and an upright tube (20) with a pivoting portion (40) for mating with the lugs (13). Neither of the tubes (10, 20) is a spinal fixation rod, nor can they be used in the spine. A spinal fixation rod is a device known in the art that is implanted in the spine to correct various deformities of the spine. The bicycle handlebars of Lai certainly cannot be considered to be a spinal fixation rod. Accordingly, claims 1, 42, 43, and 46, as well as claims 2, 13-20, and 48-49 which depend therefrom, distinguish over Lai.

*(2) U.S. Patent No. 4,433,677 of Ulrich*

Claims 46, 48, and 49 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,433,677 of Ulrich.

Claim 46 is directed to a spinal fixation device including a first elongate element having a clamping mechanism formed on a terminal end thereof, and a second elongate element having a terminal end adapted to be received by the clamping mechanism on the first elongate element. The device also includes a fastening element adapted to engage and close the clamping mechanism such that the second elongate member can be maintained in a fixed position relative to the first elongate member.

Ulrich does not teach all of the features of claim 46. Specifically, Ulrich does not teach an elongate element with a clamping mechanism formed thereon, and a fastening element adapted to engage and close the clamping mechanism. Rather, as shown in FIGS. 3 and 4, Ulrich discloses two bone screws (1), each with a head (9) formed thereon and including a bore. The bone screws (1) are mated together with a bolt disposed through the bores in the heads (9). Neither of the screws (1) includes any type of a clamping mechanism formed thereon for receiving the other of the screws (1). The screws (1) are simply elongate cylinders with a flatten circular portion at one end forming the head (9) without any additional features that could be used to clamp the screws (1) together. Accordingly, independent claim 46, as well as claims 48 and 49 which depend therefrom, distinguish over Ulrich.

(3) *U.S. Patent No. 6,007,536 of Yue*

Claims 1, 2, 7-9, 13-16, 20, 42, and 43 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue.

Claim 1 recites a spinal fixation device having a first elongate member with a female connector, a second elongate member with a male connector, and a fastening member adapted to *mate to at least one of the male and female connectors* to lock the members relative to one another. Claim 42 similarly recites a spinal fixation device having a fastening element adapted to extend into at least one of the connecting features formed on the terminal ends of first and second elongate members. Yue does not teach a fastening member as required by claims 1 and 42. Yue discloses a blade (1) having gears (3) formed thereon that mate with corresponding gears formed on a side plate (2). The blade (1) is inserted into bone, and the plate (2) is mated to bone with screws extending through the plate (2) into the bone. Neither the gears (3) nor the screws extending through the plate (2) mate to a male or female connector to lock them relative to one another. The gears (3) are the only portion of the Yue device that could be considered to form the male and female connectors, as recited in claim 1, as the gears are disposed on the ends of the blade (1) and the plate (2) and are adapted to fit together. Yue, however, does not include a fastening member that mates to at least one of the gears (3) to lock the gears relative to one another. As explained in Applicants' previous response, the gears are maintained in a locked position by mating the blade and the plate to bone.

Claims 1, 42, and 43 also recite that at least one of the first and second elongate members of the spinal fixation device is a spinal fixation rod. Yue does not teach a spinal fixation device having a spinal fixation rod. Instead, Yue discloses an orthopedic plate for use in correcting problems with the long bones of the body, such as the shoulder, knee, ankle, and hip. As stated above, a spinal fixation rod is a device known in the art that is implanted in the spine to correct various deformities of the spine, and neither the blade nor the plate of Yue can be considered to be a spinal fixation rod.

Accordingly, claims 1, 42, and 43, as well as claims 2, 7-9, 13-26, and 20 which depend therefrom, distinguish over Yue and represent allowable subject matter.

***Claim Rejections under 35 U.S.C. §103***

*(1) U.S. Patent No. 6,007,536 of Yue*

Claims 10, 47, and 50 are rejected under 35 U.S.C. §103(a) as being unpatentable over Yue.

As discussed above, independent claim 1 distinguishes over Yue. Thus, claim 10 is allowable at least because it depends from allowable claim 1.

Claims 47 and 50 depend from claim 46, which likewise distinguishes over Yue. As previously explained, claim 46 requires a clamping mechanism formed on a terminal end of a first elongate element. Yue does not teach a first elongate element having a clamping mechanism formed on a terminal end thereof. Neither the blade (1) nor the plate (2) includes any type of clamping mechanism for receiving a terminal end of a second elongate element. The blade (1) and the plate (2) merely include gears formed on the terminal ends thereof. They do not include a mechanism by which one of the blade (1) and plate (2) receives and clamps on to the other. Accordingly, independent claim 46 distinguishes over Yue. Claims 47 and 50 are therefore allowable at least because they depend from allowable claim 46.

*(2) U.S. Patent No. 4,433,677 of Ulrich*

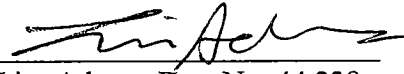
Claims 47 and 50 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ulrich. As previously discussed, independent claim 46 distinguishes over Ulrich. Thus, claims 47 and 50 are allowable at least because they depend from allowable claim 46.

***Conclusion***

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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